

K240984 i-STAT hs-Tnl cartridge with the i-STAT 1 SystemJan 3, 2025
268 days to decisionK240984 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k240984/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Immunoassay Method, Troponin Subunit (MMI) |
| Date received | Apr 10, 2024 |
| Decision date | Jan 3, 2025 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Abbott Point of Care, Inc. |
| Location | Princeton, NJ, US |
| Contact | Jacquelyn Gesumaria |
| 510(k) history | 19 submissions · 19 cleared · 2011-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240984/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026